

JC02 Rec'd PCT/PTC 01 SEP 2005 PCT

PATENT
Docket No.: 20747/270 (ARDBW/P29257US)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Axel Thomson)
Serial No. : 10/528,267)
Cnfrm. No. : To Be Assigned)
Filed : September 17, 2003)
For : A METHOD OF PROTECTING A PATIENT)
FROM POSSIBLE ADVERSE EFFECTS OF)
INHIBITION OF THE SHH-SIGNALLING)
PATHWAY BY SUPPRESSING)
TESTOSTERONE OR ITS EFFECTS IN THE)
PATIENT)

Examiner: To Be Assigned J. Ha
Art Unit: To Be Assigned 1654

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97-1.98

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§ 1.97-1.98, applicant hereby brings to the attention of the United States Patent and Trademark Office, the enclosed references listed on the attached PTO/SB/08 form.

Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. Patents (i.e., Reference Cite Nos. 1-2) are not enclosed. Copies of all other listed references (i.e., Reference Cite Nos. 3-67) are enclosed herewith.

Pursuant to 37 CFR § 1.97(b)(3), no fee is required. If additional fees are required, however, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 14-1138.

Respectfully submitted,

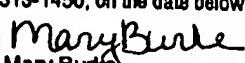
Date: August 29, 2005


Edwin V. Merkel

Registration No. 16,49,087

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Date: 8/30/05 | 
Mary Burke

NIXON PEABODY LLP
Clinton Square, P.O. Box 31051
Rochester, New York 14603-1051
Telephone: (585) 263-1128
Facsimile: (585) 263-1600

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Substitute for form 1449B/PTO				<i>Complete if Known</i>	
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				First Named Inventor	Axel Thomson
				Group Art Unit	To Be Assigned 1654
				Examiner Name	To Be Assigned J. Ha
Sheet	2	of	6	Attorney Docket Number	20747/270 (ARDBW/P29257US)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

3

of

6

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	41	LAMM et al., "Mesenchymal Factor Bone Morphogenetic Protein 4 Restricts Ductal Budding and Branching Morphogenesis in the Developing Prostate," <i>Dev. Biol.</i> 232:301-314 (2001)		
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	45	NOGAWA et al., "Bud Formation Precedes the Appearance of Differential Cell Proliferation During Branching Morphogenesis of Mouse Lung Epithelium In Vitro," <i>Dev. Dyn.</i> 213:228-235 (1998)		
↓	46	OLUMI et al., "Carcinoma-Associated Fibroblasts Direct Tumor Progression of Initiated Human Prostatic Epithelium," <i>Cancer Res.</i> 59:5002-5011 (1999)		

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	48	PARSONS et al., "p63 Protein Expression is Rare I Prostate Adenocarcinoma: Implications for Cancer Diagnosis and Carcinogenesis," <i>Urology</i> 58:619-624 (2001)		
	49	PATHI et al., "Comparative Biological Responses to Human Sonic, Indian, and Desert Hedgehog," <i>Mech. Dev.</i> 106:107-117 (2001)		
	50	PEPICELLI et al., "Sonic Hedgehog Regulates Branching Morphogenesis in the Mammalian Lung," <i>Curr. Biol.</i> 8:1083-1086 (1998)		
	51	PERRITON et al., "Sonic hedgehog Signaling from the Urethral Epithelium Controls External Genital Development," <i>Dev. Biol.</i> 247:26-46 (2002)		
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	53	ROELINK et al., "Floor Plate and Motor Neuron Induction by <i>vhh-1</i> , a Vertebrate Homolog of hedgehog Expressed by the Notochord," <i>Cell</i> 76:761-775 (1994)		
	54	RUIZ I ALTABA et al., "Gli and Hedgehog in Cancer: Tumours, Embryos and Stem Cells," <i>Nat. Rev. Cancer</i> 2:361-372 (2002)		
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	56	STONE et al., "The Tumour-Suppressor Gene <i>Patched</i> Encodes a Candidate Receptor for Sonic Hedgehog," <i>Nature</i> 384:129-134 (1996)		
	57	SUGIMURA et al., "Keratinocyte Growth Factor (KGF) Can Replace Testosterone in the Ductal Branching Morphogenesis of the Rat Ventral Prostate," <i>Int. J. Dev. Biol.</i> 40:941-951 (1996)		
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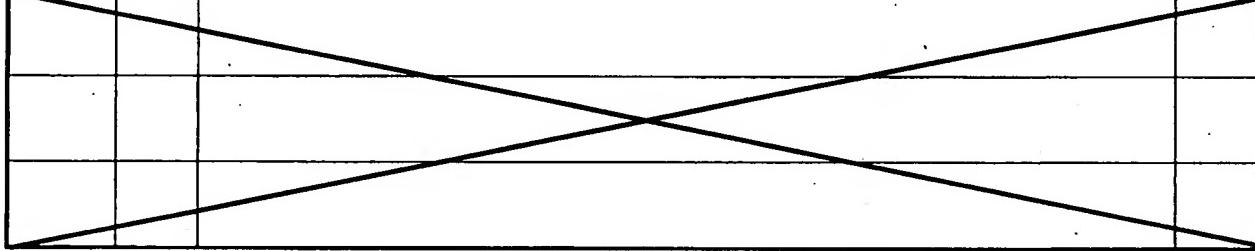
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	60	TAKEDA et al., "Construction of Chimaeric Processed Immunoglobulin Genes Containing Mouse Variable and Human Constant Region Sequences," <i>Nature</i> 314:452-454 (1985)		
	61	THOMSON & CUNHA, "Prostatic Growth and Development are Regulated by FGF10," <i>Development</i> 126:3693-3701 (1999)		
	62	THOMSON et al., "Analysis of Growth Factor and Receptor mRNA Levels During Development of the Rat Seminal Vesicle and Prostate," <i>Development</i> 124:2431-2439 (1997)		
	63	THOMSON et al., "The Role of Smooth Muscle in Regulating Prostatic Induction," <i>Development</i> 129:1905-1912 (2002)		
	64	TOTTEN et al., "Microscopic Differential Diagnosis of Latent Carcinoma of Prostate," <i>Arch. Pathol.</i> 55:131-141 (1953)		
	65	WANG et al., "Cell Differentiation Lineage in the Prostate," <i>Differentiation</i> 68:270-279 (2001)		
	66	WINTER & MILSTEIN, "Man-made Antibodies," <i>Nature</i> 349:293-299 (1991)		
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	38	KIM et al., "Pancreas Development is Promoted by Cyclopamine, a Hedgehog Signaling Inhibitor," <i>Proc. Natl. Acad. Sci. USA</i> 95:13036-13041 (1998)			
	39	KÖHLER & MILSTEIN, "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity," <i>Nature</i> 256:495-497 (1975)			
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/528,267
				Filing Date	September 17, 2003
				First Named Inventor	Axel Thomson
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	5	of	6	Attorney Docket Number	20747/270 (ARDBW/P29257US)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	47	ORLANDI et al., "Cloning Immunoglobulin Variable Domains for Expression by the Polymerase Chain Reaction," <i>Proc. Natl. Acad. Sci. USA</i> 86:3833-3837 (1989)			
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	53	ROELINK et al., "Floor Plate and Motor Neuron Induction by <i>vhh-1</i> , a Vertebrate Homolog of <i>hedgehog</i> Expressed by the Notochord," <i>Cell</i> 76:761-775 (1994)			
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/528,267
Sheet	6	of	6	Filing Date	September 17, 2003
				First Named Inventor	Axel Thomson
				Group Art Unit	To Be Assigned
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				Attorney Docket Number	20747/270 (ARDBW/P29257US)

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	59	SUKEGAWA et al., "The Concentric Structure of the Developing Gut is Regulated by Sonic Hedgehog Derived from Endodermal Epithelium," <i>Development</i> 127:1971-1980 (2000)			
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	64	TOTTEN et al., "Microscopic Differential Diagnosis of Latent Carcinoma of Prostate," <i>Arch. Pathol.</i> 55:131-141 (1953)			
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10/528267

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PATENT

Docket No.: 20747/270 (ARDBW/P29257US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Axel Andreas THOMSON)
U. S. Serial No:	To be assigned)
Filed:	Herewith)
PCT International Application No:	PCT/GB2003/004117)
Filed:	17 September 2003)
For :	A METHOD OF PROTECTING A) PATIENT FROM POSSIBLE) ADVERSE EFFECTS OF INHIBITION) OF THE SHH-SIGNALLING) PATHWAY BY SUPPRESSING) TESTOSTERONE OR ITS EFFECTS) IN THE PATIENT)

INFORMATION DISCLOSURE STATEMENT

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Dear Sir:

In compliance with 37 C.F.R. 1.56, 1.97, and 1.98, published art included in the International Search Report (copy enclosed) of the corresponding PCT application, is cited for consideration and listed on the enclosed PTO-1449 form as references 1-3. These references are relevant for the reasons given in the search report.

Because copies of the references 1-3 should have been transferred by the International Searching Authority ("ISA"), duplicate copies are not enclosed herewith. Should the U.S. Patent and Trademark Office ("PTO") require copies of references 1-3 from

10/528267

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applicants (i.e., the ISA has not provided them), the PTO should contact the undersigned representative directly.

It is respectfully requested than an Examiner-initialed copy of this form be returned to the undersigned.

Respectfully submitted,

Date: March 17, 2005



Edwin V. Merkel
Registration No. 40,087

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Clinton Square, P.O. Box 31051
Rochester, New York 14603-1051
Telephone: (585) 263-1128
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	To Be Assigned <i>10/528267</i>
Sheet	1	of	1	Filing Date	Herewith
				First Named Inventor	Axel Andreas Thomson
				Art Unit	To Be Assigned 1654
				Examiner Name	To Be Assigned J. Ha
				Attorney Docket Number	20747/270 (ARDBW/P29257US)

U.S. PATENT DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	U.S. Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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/JH/	1	Berman et al., "Medulloblastoma growth inhibition by Hedgehog pathway blockade", <u>Science</u> , 297(5586):1559-1561 (2002).			
/JH/	2	Podlasek et al., "Prostate development requires Sonic hedgehog expressed by the urogenital sinus epithelium", <u>Developmental Biology</u> , 209 (1):28-39 (1999).			
/JH/	3.	Bergman et al., "Inhibition of prostate morphogenesis by the sonic hedgehog pathway inhibitor cyclopamine", <u>Journal of Urology</u> , 163(4 suppl.):204 (2000).			

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